



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#13

Applicant: Mark UDEN et al.

Title: RETROVIRAL VECTORS COMPRISING FUNCTIONAL AND NON-FUNCTIONAL SPLICE DONOR AND SPLICE ACCEPTOR SITES

Appl. No.: 09/937,295

Filing Date: 11/29/2001

Examiner: Nguyen, Quang

Art Unit: 1636

RECEIVED
MAY 01 2003
TECH CENTER 1600/2900

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

This paper is a response to the restriction requirement set forth in the Office Action mailed on March 26, 2003.

The Examiner has restricted pending claims 1-49 into eleven separate groups, including the following:

- Group I: claims 1-34, drawn to a retroviral vector comprising a functional splice donor (FSDS) site and a functional splice acceptor (FSAS) site, wherein the FSDS and FSAS flank a first nucleotide sequence of interest (NOI), wherein the FSDS is upstream of the FSAS, wherein the retroviral vector is derived from a retroviral pro-vector; a retroviral particle obtainable from the retroviral vector; a cell transfected or transduced with the retroviral vector; use of the retroviral vector for manufacturing a pharmaceutical composition; and a retroviral pro-vector corresponding to the retroviral vector;
- Group III: claim 37, drawn to the use of a functional intron to restrict expression of one or more NOIs within a target cell;

- Group IV: claim 38, drawn to the use of a reverse transcriptase to deliver a first NS from the 3' end of a retroviral vector such that a functional intron is created upon transduction;
- Group VII: claim 43, drawn to a lentiviral vector system wherein the lentiviral vector comprises or is capable of delivering a split-intron configuration;
- Group IX: claim 45, drawn to vectors or plasmids based on or obtained from any one or more of pE1sp1A, pCl-Neo, pE1RevE, pE1HORSE3.1, pE1PEGASUS4, pCL-Rab, pE1Rab;
- Group X: claim 48, drawn to a self-inactivating (SIN) retroviral vector comprising a FSDS and a FSAS wherein the FSDS and FSAS flank a first NOI, wherein the FSDS is upstream of the FSAS, wherein the retroviral vector is derived from a retroviral pro-vector; such that a retroviral vector can not be packaged as a result of the reverse transcription of the retroviral pro-vector at a target site;
- Group XI: claim 49, drawn to a retroviral vector capable of differential expression of NOIs in target cells.

Applicants hereby provisionally elect, with traverse, to prosecute Group I, claims 1-34 and 36.

As a basis for traversal, Applicants submit that the Examiner failed to establish a need for restriction. The criteria for a proper restriction requirement, according to MPEP § 803, are (1) that the inventions must be independent or distinct as claimed, and (2) that there must be a serious burden on the Examiner to examine the entire application. In this case, the Examiner has failed to demonstrate that a more serious examination burden exists absent restriction. Indeed, the search and examination of Group I will necessarily entail consideration of Groups III, IV, VII, IX, X and XI as well.

Group I relates to a retroviral vector comprising a functional splice donor site and a functional splice acceptor site, and obtained from a described pro-vector. Examination of such a retroviral vector necessarily will include consideration of the vector's production via reverse transcriptase from a provector (Group IV). Additionally, examination of the retroviral vector will include consideration of the placement of functional introns (Group III), as recited in claims 22-23 of Group I. This, in turn, will require consideration of the resulting

retroviral vector capable of differential expression of NOIs (Group XI). Examination of the retroviral vector of Group I will further include consideration of lentiviral vector-derived components such as EIAV-derived plasmids and envelope plasmids (Group IX), as well as self-inactivating LTR retroviral components (Group X).

Therefore, Groups I, III, IV, VII, IX, X, and XI are inextricably linked, and the combined examination of these groups will not impose an undue additional burden on the Examiner. Accordingly, Applicants believe the restriction to be improper, and respectfully request that Groups III, IV, VII, IX, X, and XI be rejoined to the elected group.

An early favorable action on the merits is awaited.

Respectfully submitted,

Date

April 29, 2003

By

[Signature] (28,665)

FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5143
Telephone: (202) 672-5538
Facsimile: (202) 672-5399

for Michele M. Simkin
Attorney for Applicants
Registration No. 34,717